

REMARKS

Claims 1-25 are currently pending. Claims 1-6 and 12-16 are withdrawn from consideration and claims 7-11 and 17-25 stand rejected. Claims 7, 17-21 are amended and claims 10-11 are cancelled herein. Support for the present claim amendments can be found throughout the application and claims as filed, for example, at page 4, lines 23-28; and original claims 10 and 11. Entry of the present amendment is respectfully requested. No new matter is presented.

Priority

The Applicant herein incorporates an amendment to the specification to provide a specific reference to U.S. Provisional Patent Application No. 60/224,447 in accordance with the request by the Office. Entry of this amendment is respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 7-11 and 17-25 stand rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to comply with the written description requirement. The Office has specifically asserted that the CIP fragment is not adequately disclosed in the claims nor the specification. However, the Office has quoted page 4, lines 23-28 of the present specification, which provides a description of the CIP fragment (*i.e.*, a peptide having an amino acid sequence from between SEQ ID NO: 4 [PTH₂₋₈₄] and SEQ ID NO: 5 [PTH₃₄₋₈₄]). As provided in the specification, a CIP fragment can comprise PTH₂₋₈₄, PTH₃₋₈₄, PTH₄₋₈₄, PTH₅₋₈₄, . . . PTH₃₂₋₈₄, PTH₃₃₋₈₄, up to and including PTH₃₄₋₈₄. *See* page 4, lines 23-28. Respectfully, the Applicant herein incorporates this description of CIP in the present claims (including specific SEQ ID NOs) to clarify the intended meaning of the term “CIP.” The considered claims are directed to methods and kits for measuring cyclase inhibiting parathyroid hormone fragment in a sample. The term cyclase inhibiting PTH peptide fragment, as used in the present specification, refers to CIP, as indicated in the passage quoted by the Office. With regard to the relation of the terms “CIP” and “CIP fragment,” the Applicant respectfully directs the Office’s attention to the enablement discussion below. In light of the present amendment and discussion, the Applicant respectfully traverses the present written description rejection and withdrawal is requested.

Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 7-11 and 17-25 stand rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to comply with the enablement requirement. The Office has asserted that the “disclosure fails to teach what the cyclase inhibiting parathyroid hormone fragment is.” It seems to the Applicant that the Office has taken the position that the terms “CIP” and “CIP fragment” refer to different entities, having different characteristics. In contrast, both “CIP” and “CIP fragment,” for purposes of the present application and this discussion, refer to a peptide having an amino acid sequence from between SEQ ID NO: 4 [PTH₂₋₈₄] and SEQ ID NO: 5 [PTH₃₄₋₈₄]. The term “fragment” is occasionally indicated in the specification together with the term “CIP” and merely refers to CIP’s status as a PTH peptide fragment. Thus, the Applicant respectfully asserts that both “CIP” and “CIP fragment” are defined in the specification and this definition is presently incorporated in the pending claims. As such, the Applicant respectfully asserts that the claims are enabled as currently presented. Withdrawal of the present rejection is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 7-11 and 17-25 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite. The Office has specifically indicated that the recitation of the term “sufficient” in claim 7 renders the claim indefinite. Claim 7 is amended herein to more distinctly describe the claimed subject matter, which amendment incidentally removes the term objected to by the Office. Accordingly, the Applicant respectfully requests withdrawal of this rejection.

With regard to claims 10 and 11, the Office has cited multiple bases that purportedly render these claims indefinite. As claims 10 and 11 are cancelled herein, the present rejection as it applies to these claims is rendered moot and withdrawal is respectfully requested.

With regard to claim 17, the Office has indicated that the term “substantially” is a relative term which renders the claim vague and indefinite. Although the Applicant respectfully disagrees with the Office that the term “substantially” renders the claim indefinite, claim 17 is amended herein to remove the phrase objected to by the Office. Thus, the Applicant respectfully requests withdrawal of this rejection. It is believed that the presently described amendment to claim 17 merely clarifies certain aspects of the present invention and, as this amendment is not made for reasons related to patentability, it does not narrow the intended scope of the claims.

With regard to claim 18, the Office has indicated that insufficient antecedent basis exists for the phrase “the C-terminal portion of CIP.” In response, the Applicants assert that the C-terminal of CIP is an inherent aspect of a CIP of claim 17. As indicated in MPEP 2173.05(e), “inherent components of elements recited have antecedent basis in the recitation of the components themselves.” Thus, the Applicants assert that sufficient antecedent basis for the phrase “the C-terminal of CIP” is provided in the currently amended claims. Thus, the Applicant respectfully requests withdrawal of this rejection.

Restriction Status

It is noted that the Office has deemed the present Restriction final. Further, the Applicant understands that after the requirement is deemed final, a Petition under 37 CFR § 1.144 may be made to the Commissioner to review the requirement. Nevertheless, in light of the foregoing discussion as it pertains to the relation of the terms “CIP” and “CIP fragment” (and the prior attempt at traversal of the restriction requirement), the Applicant invites the Office to withdraw the finality of the restriction requirement and to reconsider the basis for restricting previous Groups I (claims 1-6) and II (claims 7-11 and 17-18 (now further including claims 19-25)). Again, the Applicant asserts that no undue search burden is present between these Groups as the structures do not differ. Recombination of Groups I and II is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 532212001500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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